

Claims 1-33 are present in this application and have been subjected to restriction by the Examiner under 35 U.S.C. §121 (37 C.F.R. §1.142) as follows:

- I: Claims 1-12 and 27, drawn to a method for detecting an inhibitor of interaction between two or more binding partners, classified in class 436, subclass 501.
- II: Claims 13-25 and 28-33, drawn to an assay device, classified in class 422, subclass 50.
- III. Claim 26, drawn to the use of binding partnership, classified in class 435, subclass 7.1.

Accordingly, it is the Examiner's position that each group of claims set forth above requires individual consideration as to patentability; each group has been asserted to be patentably distinct.

As indicated, and in order to be fully responsive to the Examiner's requirement for restriction, applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, Claims 1-12 and 27, drawn to a method for detecting an inhibitor of interaction between two or more binding partners and reserve the right to file a divisional application(s) directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof for the following reasons.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. 35 U.S.C. §121, first sentence (emphasis added).

The implementing regulations of the United States Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are

both independent and distinct, 37 C.F.R. §§1.141-142. Without independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims of Groups I, II and III which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. The claims of Group I include a method for detecting an inhibitor between two or more binding partners. The claims of Group II are directed to an assay device which detects an inhibitor of interaction between members of a binding partnership comprising two or more binding partners, and the claim of Group III is directed to the use of binding partners for the detection of an inhibitor of interaction between binding partners. Applicants submit that the claims in each group are interrelated in that the claims all include the detection of an inhibitor interaction between binding partners.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicant has done here. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. *In re Kuehl*, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily

imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts.

It is vital to all applicant's that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicant respectfully urges the

Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

The Examiner justified the restriction requirement in this case by alleging that the three groups of claims have acquired a separate status in the art by virtue of the fact that each group of claims can be found in different subclasses. This basis does not justify the restriction requirement in this application.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims he assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classification and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to consideration of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass.

These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

A determination to make this restriction final requires that the Examiner find that each of the groups identified respectively define a separate patentable invention, one from the other. Applicants believe that the foregoing has not been done since all the claims are directed to the detection of an inhibitor of interaction between binding partners.

Hence, it is again respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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